UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*** **Case No. 1:18-OP-45090** ***The County of Cuyahoga v. Purdue Pharma L.P., et al.*** **Case No. 17-OP-45004**	**MDL NO. 2804** **Case No. 17-md-2804** **Hon. Dan Aaron Polster**

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF DAVID A. KESSLER, M.D. AND MATTHEW PERRI, III BS PHARM, Ph.D., RPh

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INTRODUCTION

Plaintiffs' lawyers told one of their proffered marketing experts, Dr. Matthew Perri III, to assume that all of the Manufacturers'[1] prescription opioid marketing was false or misleading, and then asked him to opine whether that assumed false or misleading marketing violated any industry standards. It does not take a higher degree in pharmacy and marketing to guess the punch-line: Perri adopts their sweeping and unsupported assumption and concludes that the Manufacturers violated industry standards. Compounding the problem, when answering Plaintiffs' loaded question, Perri does not measure the Manufacturers' marketing by reference to the FDA's comprehensive regulatory scheme; instead, he uses an ill-defined and generic "principles of marketing" methodology that another federal court has excluded as unreliable. *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at *11–12 (N.D. Ala. Dec. 4, 2014), *aff'd*, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014) (excluding Perri's testimony and supplemental report). The Court should exclude Perri's opinions in their entirety because he lacks a reliable methodology and his opinions do not "fit" the facts and law governing the case as framed by Plaintiffs.

Plaintiffs' other proffered marketing expert, Dr. David A. Kessler, similarly seeks to offer testimony that is beyond his expertise, divorced from any regulatory finding or objective standard,

[1] In the Complaints, Plaintiffs lump Noramco together with J&J and its other affiliated entities, all Marketing Defendants, or all Defendants collectively even though Noramco is an active pharmaceutical ingredient supplier, and not a finished drug product manufacturer. Accordingly, Noramco did not manufacture, package, brand, market, promote, distribute or sell the finished medications at issue in this litigation. This explains why Plaintiffs sought no discovery against Noramco in the Track One cases. Indeed, to Noramco's knowledge, the only Track One discovery that even mentioned Noramco specifically is the undisclosed and improper expert testimony of Dr. Kessler described in this brief. And with the exclusion of this legally defective testimony, the record is devoid of any evidence related to Noramco at all, let alone evidence of any wrongdoing committed by Noramco. *See* Noramco's Memorandum in Support of Motion for Judgment on the Pleadings Or, in the Alternative, Summary Judgment.

and non-expert in nature. Since leaving government service over twenty years ago, Kessler has become a professional witness for Plaintiffs' attorneys suing pharmaceutical companies. He has tried to offer opinions similar to those he has disclosed here in a number of cases. Courts around the country have not hesitated to exclude or limit Kessler's testimony to his narrow area of expertise. *See, e.g., Wells v. Allergan, Inc.*, No. Civ-12-973-C, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013); *In re Prograf Antitrust Litig.*, No. 1:11-MD-02242, 2014 WL 7641156 (D. Mass. Dec. 23, 2014); *Drake v. Allergan, Inc.*, No. 2:13-cv-234, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628-29 (S.D.W.Va. 2013).

Perri and Kessler intend to testify that it was improper for the Manufacturers to market prescription opioids as safe and effective to treat chronic pain—despite this being a use approved by the FDA to this day. In response to the Manufacturers' preemption defense, Plaintiffs told this Court at the pleading stage that this case is not about whether the Manufacturers falsely claimed opioids were "safe and effective for the long-term treatment of chronic non-cancer pain." R&R (Doc. #1025), at 49. Now, however, Plaintiffs offer an expert to give precisely the opinion Plaintiffs disclaimed. They should not be permitted to do so.

The Court should also exclude or limit the opinions of Perri and Kessler because they violate several other aspects of Federal Rule of Evidence 702 and *Daubert*. An expert applies "scientific, technical, or other specialized knowledge" to "assist the trier of fact to understand the evidence or to determine a fact in issue." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993). It is not an expert's job to narrate the evidence and tell the jury what it means. That is the role of counsel at closing argument. It is not an expert's job to draw inferences about the knowledge, motives, or intent of individuals or organizations. That role belongs to the

jury. And it is not an expert's job to instruct the jury on the law or offer legal conclusions. That role belongs to the Court. Plaintiffs' experts violate these rules.

First, Perri and Kessler attempt to step into counsel's shoes to tell their "marketing story,"—*i.e.*, a factual narrative to the jury that consists of nothing more than selective quotes from documents and depositions. Neither proposed expert has any specialized knowledge or expertise related to the Manufacturers' internal company policies and procedures. The jury is able to read these documents and exercise its fact-finding responsibility without an expert witness acting as a document delivery vehicle. Other courts have prevented Kessler and Perri from offering similar narratives. *See, e.g., Wells v. Allergan, Inc.*, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013) (Kessler); *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at *11–12 (N.D. Ala. Dec. 4, 2014), *holding aff'd*, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014) (Perri). The Court should bar the testimony here as well.

Second, both witnesses want to offer their opinions about the knowledge, motivation, state of mind, and/or intent of the Manufacturers and their employees. This too is improper, and courts have excluded similar opinions in the past. *See, e.g., Wells*, 2013 WL 7208221, at *3 (excluding Kessler's corporate intent opinion); *In re Prograf Antitrust Litig.*, 2014 WL 7641156, at *2 (excluding Kessler's opinions about corporate state of mind and motivation). This Court excluded similar corporate intent expert testimony in the *Gadolinium* litigation. *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, MDL No. 1909, 2010 WL 1796334, at *12-13 (N.D. Ohio May 4, 2010) (Polster, J.).

Kessler has two other improper opinions that require exclusion. Kessler proposes to assume the Court's role by giving the jury his legal conclusions about the Manufacturers' duties and responsibilities under state and federal law. But it is for the Court, not Kessler, to instruct the

jury on the law. Courts routinely limit Kessler's testimony and bar his legal opinions, including the interplay between FDA regulations and state tort law, and whether a company complied with federal or state law. *In re Prograf Antitrust Litig.*, 2014 WL 7641156, at *2; *Drake*, 2014 WL 5392995, at *6; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 628-29; *Wells*, 2013 WL 7208221, at *1. Kessler's legal opinion testimony is improper and should be excluded here too. Finally, Kessler also offered at his deposition an opinion about one Defendant—Noramco—that he did not disclose in his report. Rule 37(c) requires exclusion of this undisclosed opinion.

BACKGROUND

I. Matthew Perri

Perri is a pharmacist by training; his Ph.D. was a dual concentration on Pharmacy and Marketing.[2] He teaches courses in healthcare and pharmaceutical marketing at the University of Georgia.[3]

Plaintiffs hired Perri to evaluate Defendants' marketing of prescription opioids,[4] with the instruction that he was to ***assume the Manufacturers' marketing messages were "false, misleading, inaccurate, or designed to misstate the risks and benefits" of the medications***.[5] Starting with that assumption, Perri concludes that the goal of marketing is to increase sales, the Manufacturers marketed their products extensively to increase prescriptions, and the Manufacturers' marketing "failed to adhere to industry standards in their marketing of opioids."[6] Perri does not opine that "any particular defendant in this case violated FDA regulations."[7] Rather,

[2] Expert Report of Matthew Perri, III, BS Pharm, Ph.D., RPh, dated March 25, 2019 ("Perri Rep."), at 1 (attached s Ex. 3).
[3] Perri Rep. at 1.
[4] *Id.*
[5] *Id.* at 138.
[6] *Id.* at 7-8.
[7] Deposition of Matthew Perri, III, BS Pharm, Ph.D., RPh, April 23, 2019 ("Perri Dep."), at 45:1-10 (excerpts attached as Ex. 4).

he applies his own standard, based on his own undefined "principles of marketing," to conclude the marketing was improper—not surprising, since the lawyers instructed him to assume all of it was false or misleading.

II. David Kessler

Kessler served as the Commissioner of the U.S. Food and Drug Administration in the 1990s.[8] Kessler testified that in 1994, he personally chose to allow Duragesic to be marketed for chronic pain and did not limit its indication to cancer pain.[9] And it was under his watch as Commissioner that the FDA first approved OxyContin as safe and effective in December 1995. Since leaving the FDA in 1997, Kessler has spent much of the last twenty years as a professional witness for Plaintiffs' attorneys suing pharmaceutical companies. He concedes he has "made millions of dollars" testifying against pharmaceutical companies.[10] Kessler has no educational background in marketing.[11] When he worked for the FDA he was never part of the Division of Drug Marketing, Advertising, and Communications ("DDMAC") (now called the Office of Prescription Drug Promotion ("OPDP")), the division of the FDA related to marketing.[12]

In his report, Kessler purports to offer a legal tutorial on the Manufacturers' "responsibilities" under the Food Drug and Cosmetics Act ("FDCA").[13] He then surveys marketing materials and internal company documents, draws personal opinions about the accuracy of the Manufacturers' marketing and speculates about the state of mind or corporate intent of

[8] Export Report of David A. Kessler, M.D., dated March 26, 2019 ("Kessler Rep."), at 10 (attached as Ex. 1).
[9] Deposition of David A. Kessler, M.D., April 25 and April 26, 2019 ("Kessler Dep."), at 253:7-13 (attached as Ex. 2).
[10] Kessler Dep. at 30:22-31:15.
[11] Kessler Rep. at App'x A.
[12] Kessler Dep. at 29:16-30:12
[13] Kessler Rep. at 14-25.

individual Manufacturers,[14] and returns to broad legal conclusions that the Manufacturers' marketing "misbranded" the products in violation of the FDCA, or otherwise departed from FDA standards in a way that contributed to "a shift in the practice of medicine with regards to the use of opioids in the treatment of pain."[15]

ARGUMENT

I. PERRI'S OPINIONS ARE NOT BASED ON A RELIABLE METHODOLOGY AND DO NOT FIT THE FACTS AND LAW RELEVANT TO PLAINTIFFS' CLAIMS.

The Court should exclude Perri's opinions for two reasons. First, he uses a nebulous "principles of marketing" standard that another federal court rejected as unreliable, and this Court should do the same. Second, Perri's opinions do not "fit" this case. He starts from the lawyers' assumption that all marketing was false or misleading. There is no evidence in the record that ***all*** marketing was misleading. Yet Perri accepts this unsupported lawyers' assumption as true, and it dictates Perri's opinion that the Manufacturers violated industry standards with the marketing message that "[o]pioids are effective for, and improve functioning in, patients taking them for long-term and chronic pain."[16] This is a theory Plaintiffs' counsel disclaimed, with good reason: The FDA has approved—and continues to approve—opioids as safe and effective for the treatment of chronic non-cancer pain.

A. Perri's nebulous "principles of marketing" methodology does not withstand scrutiny.

Perri bases his opinion that the Manufacturers violated "industry standards" not on the most significant and controlling industry standard applicable to pharmaceutical marketing—the FDA's regulation of pharmaceutical labeling and promotion—but rather on what he describes as

[14] *Id.* at 28-31; *see also infra*, notes 26-30 and accompanying text.
[15] Kessler Rep. at 315-320.
[16] Perri Rep. at 81.

the "principles of marketing." He does not identify any published, objective standard used to apply his "principles of marketing" methodology to this case. He claims instead to base his opinion on "generally accepted principle[s]."[17] Perri makes passing reference to the Code on Interactions with Healthcare Professionals published by Pharmaceutical Research and Manufacturers of America (PhRMA), an industry group—but apart from citations to the PhRMA Code in two footnotes of his report, he offers no opinions about its standards.[18] Perri may have "general" familiarity with the FDA regulations related to prescription medication advertisements, but they are not the basis of his opinions and he cites no FDA regulations or other FDA guidance.[19] Nor does Perri explain how his general "principles of marketing" apply in the highly regulated and unique pharmaceutical industry.

This is not the first time Perri has relied on general "principles of marketing" to support his opinions. Another federal court excluded Perri's opinion because he made "no attempt to explain how his 'universal principles of marketing' methodology [had] any bearing on [the defendant's] hospice business objectives." *AseraCare Inc.*, 2014 WL 6879254, at *11–12. This same flaw requires the exclusion of Perri's opinions in this case. He uses a general, ill-defined standard he created himself—and adopted the Plaintiffs' lawyers' assumption that all marketing is false or misleading—to necessarily arrive at his preordained opinion. Perri has not done any independent or systematic review of the Manufacturers' marketing but simply follows the Plaintiffs' lawyers' instruction and assumes it is all unlawful. Stripped of this assumption, he lacks any reliable and relevant methodology to support the contention that the Manufacturers violated industry standards.

[17] Perri Dep. at 90:8-23.
[18] Perri Rep. at 18 n.35, 21 n. 38.
[19] Perri Dep. at 90:24-91:25; *see also* Perri Rep. at 58 (stating "The FDA regulates branded marketing" but then failing to identify the specific standards or regulations).

B. Perri's opinion does not "fit" the facts and law of this case.

Perri claims that he is not criticizing opioids' FDA-approved labeling as inaccurate or deceptive.[20] Yet he makes a naked attack on the FDA-approved indication of certain opioid medications for ***daily, around-the-clock, long-term opioid treatment*** by claiming that the Manufacturers' marketing improperly expanded "the indication for patients who require opioid therapy for 'more than a few days' into 'chronic use,'" and that the labeling omitted "side-effects associated with long-term use."[21] Indeed, as recently as this month the FDA again reemphasized the importance of opioids as a treatment option for chronic pain management:

> It is important to consider the potential repercussions of well-meaning attempts to address the opioid crisis without adequate scientific evidence to support such actions. Inadequately treated chronic pain has consequences, and in general, the use of higher doses of opioid analgesics often occurs in the setting of chronic pain, as patients titrate to an effective dose. Robust evidence supports that chronic pain itself, regardless of type, is an important independent risk factor for suicidality, as chronic pain patients are at least twice as likely to report suicidal behaviors or to complete suicide.[22]

FDA approval for "daily, around-the-clock, long-term opioid treatment" preempts any claim that would impose a conflicting obligation or require the Manufacturers to "stop selling" opioids for chronic pain. *See generally Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-89 (2013) (rejecting "stop selling" rationale as incompatible with preemption doctrine).

Perri's opinion also contradicts Plaintiffs' theory of the case. In an effort to avoid Manufacturers' preemption defense, Plaintiffs' opposition to the motion to dismiss claimed that they "do not challenge the FDA-approved labeling of any of Defendants' products." Plaintiffs'

[20] Perri Dep. at 155:11-160:9; 193:7-195:17.
[21] Perri Rep. at 81.
[22] FDA Briefing Document, *Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)*, (June 11-12, 2019), at 10 (attached as Ex. 5).

Opp. to Mot. to Dismiss, at 116 (Doc. #654). Based on this representation, Magistrate Judge Ruiz declined to find Plaintiffs' claims preempted and concluded: "Plaintiffs dispute that their claims are based on allegations that Defendants falsely claimed their medications were 'safe and effective for the long-term treatment of chronic non-cancer pain.'" R&R at 49 (Doc. #1025) (quoting Opp. at 115-16).

Perri's proposed testimony addresses impermissible or abandoned claims, so it fails Rule 702's "fit" requirement. "[T]here must be a 'fit' between the inquiry in the case and the testimony, and expert testimony that does not relate to any issue in the case is not relevant and therefore not helpful." *United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993); *see also Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d 470, 496 (D.N.J. 2002) (citing *Habecker v. Clark Equipment Co.*, 36 F.3d 278, 290 (3d Cir.1994)). To "fit" the case and be admissible under Rule 702, the opinion must help the jury "determine a fact in issue. This condition goes primarily to relevance." *Daubert*, 509 U.S. at 591 (1993). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* "Fit" is an issue for consideration now, for it is a "precondition to ***admissibility***" and not a question of weight. *Hutchison v. Parent*, No. 3:12-cv-320, 2015 WL 1914794, * 3 (N.D. Ohio Apr. 27, 2015) (emphasis added). Perri's opinion about the Manufacturers' alleged "expansion" of the indication to "chronic use" must be excluded because it does not "fit" the governing law or Plaintiffs' case. And if, in the alternative, Perri simply is unfamiliar with the FDA-approved indications for the Manufacturers' products, it shows that his opinion lacks a sufficient factual basis and should be excluded for that additional reason.

II. THE COURT SHOULD NOT ALLOW KESSLER AND PERRI TO PRESENT A FACTUAL NARRATIVE OR SPECULATE ABOUT THE KNOWLEDGE, INTENT, MOTIVATION, ETHICS, OR STATE OF MIND OF THE MANUFACTURERS.

A. The opinions are improper closing arguments that invade the fact-finding role of the jury.

Plaintiffs aim to use Kessler and Perri as spokesmen for Plaintiffs' "marketing story." Based on the length of their reports, it seems the witnesses intend to march through a lengthy presentation of curated and excerpted documents about which they have no personal knowledge, and then simply tell the jury what factual and legal conclusions to draw. But the jury is capable of reading the Manufacturers' documents and drawing conclusions, so this proposed testimony is not expert in nature. There also is a high likelihood of confusion and error; a "marketing story" from these witnesses, identified as "experts," will unfairly influence the jury. Indeed, both reports include lengthy factual narratives that gather soundbites from cherry-picked documents. Kessler's report contains hundreds of pages of selective quotes from the Manufacturers' documents, followed by five pages of broad assertions such as, "[i]n my opinion, Purdue utilized promotional tactics that misbranded OxyContin as a drug that is safer and more effective than it actually is."[23] Perri's report does the same but suffers from additional infirmities. Not only is Perri's lengthy recitation of the "marketing strategy for opioids," nothing more than selective excerpting of the Manufacturers' documents, many of them drafts, internal, or otherwise never used, Perri also fails to offer any distinction between the Manufacturers. Although the Manufacturers marketed different products, at different times, in different ways, with different materials, and in competition with one another, Perri treats the Manufacturers as one monolithic entity. Unless Perri is prepared to testify that each and every defendant engaged in the conduct at issue—which he apparently is

[23] Kessler Rep. at 315-320.

not—allowing him to testify globally about "Defendants' conduct" is confusing, misleading, not helpful to the jury and should be excluded. *See* Fed. R. Civ. P. 403; *United States v. Geiger*, 303 Fed. App'x 327, 329 (6th Cir. 2008) ("Like all evidence, the admissibility of expert testimony is also subject to a . . . balancing of probative value against likely prejudice under Rule 403."). Perri's report also includes a 42-page table of snippets[24] accompanied by the opinion that "Defendants violated marketing standards."[25] These narrative summaries of the evidence, as seen through the paid experts' eyes, are more akin to closing argument and usurp the role of the lawyers ***and*** the jury. Courts have not hesitated to exclude such narratives in the guise of an "expert opinion." *See, e.g., Nimely v. City of New York*, 414 F.3d 381, 398 (2d Cir. 2005).

The opinions of both Kessler and Perri have been excluded on this basis before. *See, e.g., Wells*, 2013 WL 7208221, at *2 ("Kessler may not simply rehash otherwise admissible evidence about which he has no personal knowledge") (quotations and alteration omitted); *AseraCare Inc.*, 2014 WL 6879254, at *11–12 (excluding Perri). They should be excluded here too. This type of proposed testimony is impermissible: "[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence." *Highland Capital Mgmt., L.P.* v. *Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005); *see also United States v. Kilpatrick*, 798 F.3d 365, 381 (6th Cir. 2015); *Taylor* v. *Evans*, No. 94 Civ. 8425 (CSH), 1997 WL 154010, at *2 (S.D.N.Y. Apr.1, 1997) (rejecting portions of expert testimony that consisted of "a narrative of the case which a lay juror is equally capable of constructing"). The jury "is equally capable of constructing" the facts of the case from evidence introduced through "percipient witnesses and documentary evidence." *In re Rezulin Prods. Liab. Litig.* ("*In re Rezulin*"), 309 F. Supp. 2d 531,

[24] Perri Rep. at 86-128.
[25] *Id.* at 138.

551 (S.D.N.Y. 2004). An expert's factual narrative is nothing more than improper advocacy that invades the fact-finding province of the jury. As the Fifth Circuit noted, "the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument." *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1233 (5th Cir. 1986).

Courts routinely exclude or limit expert testimony of this type. In the *Fosamax* litigation, for example, the court did not permit the regulatory expert "to merely read, selectively quote from, or 'regurgitate' the evidence." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (citations omitted). The same happened in the *Prempro* litigation, in a ruling affirmed by the Eighth Circuit. *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009). Similarly, in a medical device case, the court concluded, "the majority of [expert's] report appears to state facts that could be directly presented to the jury and then make legal conclusions. Such a role is inappropriate for an expert witness." *Miller v. Stryker Instruments, et al.*, No. CV 09-813, 2012 WL 1718825, at *12 (D. Ariz. Mar. 29, 2012). And in the *Rezulin* litigation, the court excluded an opinion that offered a selected regulatory history of the medication, because it was "nothing more than a repetition of the factual allegations in plaintiffs' complaint combined with comments amounting to [the expert's] 'spin' on the facts." *In re Rezulin*, 309 F. Supp. 2d at 551 (citations omitted). The expert, in this scenario, "'does no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct.'" *Id.* (alteration in original) (citations omitted). The same rationale led to the exclusion of testimony in another prescription medication case where the plaintiff used the "expert witness to make her closing argument rather than relate scientific conclusions." *Hogan* v. *Novartis Pharm. Corp.*, No. 06 Civ. 0260 BMC RER, 2011 WL 1533467, at *8 (E.D.N.Y. Apr. 24, 2011). The Court should reach the same result here.

B. The opinions are improper interpretations of the Manufacturers' corporate knowledge, intent, and state of mind.

Courts throughout the country have acknowledged that an expert opinion that amounts to mind-reading is not the type of "scientific, technical, or other specialized knowledge" permitted by Rule 702. Nonetheless, Kessler and Perri seek to offer testimony about the Manufacturers' knowledge, intent and state of mind. This opinion testimony is inadmissible because it is speculative and invades the province of the jury. In fact, Kessler's opinions have been excluded on this basis before. As one court concluded, "Kessler cannot be permitted to speculate as to the intent or state of mind of [the drug manufacturer or] the FDA." *See, e.g., Wells*, 2013 WL 7208221, at *3. Another court agreed: "although Dr. Kessler's years of government service may let him form good guesses about why parties petitioning FDA behave as they do, his expertise only lies on the FDA side of the regulatory process. Dr. Kessler may not speculate on why [the defendant] or anyone else acted as they did." *In re Prograf Antitrust Litig.*, 2014 WL 7641156, at *2. Likely because of these prior adverse rulings, Kessler claimed in his deposition that he was not seeking to offer testimony as to the FDA's or the Manufacturers' corporate knowledge, state of mind, or intent:

> A. That's not -- you asked me what FDA was thinking. No one can do -- no one should be able to tell you what FDA was thinking because that's a subjective state. I can tell you what the record reflects.
>
> * * *
>
> Q. Okay. And you're not -- you don't have any special training or knowledge that lets you interpret what somebody was thinking at any point in time?
>
> A. I am not a mind reader, and I would never want to do that in any form of testimony. If you ask me a question, I'll try my best to answer it.
>
> Q. And that would be true not just with regard to what FDA was thinking, but it would be true with regard to what anybody at any of the companies were thinking as well?

> A. So obviously the word "thinking," I would agree with you. But I think when there's an objective record -- so I can tell you what is stated, okay –
>
> Q. But you're not going to purport to interpret somebody's intent or their state of mind?
>
> A. I will never go to intent.[26]

But despite this claim, Kessler's report and testimony tell a different story:

- "I think your client had . . . warning letters and we can – that probably reflects at least some extent ***that the company knew***."[27]
- "[W]hat wasn't disclosed to the agency was ***the game plan*** to significantly increase the dose beyond what American medicine was using."[28]
- "***I don't think FDA has an understanding.*** Your company has stated that it did not know about the street value of oxy until 2000, 2001."[29]
- "Your -- all marketing campaigns were to distinguish and to remove the stigma associated with morphine. That was a very explicit strategy that was carried out."[30]

Perri was very clear that he too is seeking to offer testimony as to corporate intent and state of mind:

> Q. But in terms of your description here of what motivated Purdue to develop OxyContin and what Purdue's intent was with respect to development of OxyContin, that's information that you've gleaned from the documents you've looked at in this case; fair?
>
> A. That, in particular, came from the OxyContin launch plan in 1993 or '94, I believe.[31]
>
> * * *
>
> Q. What are you providing that any other person in this room or on the jury couldn't come to their own conclusion about?

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[26] Kessler Dep. at 72:6–74:10 (form objections omitted); *see also* Perri Dep. at 394:24-25 ("So as a rule, I can never know what someone was thinking").
[27] Kessler Dep. at 69:21-24 (emphasis added).
[28] Kessler Dep. at 325:20-23 (emphasis added).
[29] Kessler Dep. at 293:12–294:14, 295:6–18 9 (emphasis added).
[30] Kessler Dep. at 335:15–24.
[31] Perri Dep. at 163:3-10;

> A. So I think there's a number of things . . . . But the idea of, can the average person just look at a brochure designed for patients and be able to assess from that ***what the purpose*** of a well-orchestrated, well-defined, and aggressive marketing promise might have been, I don't think so. . .[32]

All of this testimony speaks to intent, motivation, knowledge, or state of mind and should be excluded.

This Court has also recognized that expert testimony on corporate motivation and intent is inadmissible. In the *Gadolinium* litigation, this Court precluded expert testimony about the alleged knowledge, motivations, intent or purposes of a corporate defendant, its employees, and the FDA. *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, MDL No. 1909, 2010 WL 1796334, at *12-13 (N.D. Ohio May 4, 2010) (Polster, J.). Other courts have reached the same conclusion. *See, e.g.*, *Raley* v. *Hyundai Motor Co.*, No. CIV-08-376-HE, 2010 WL 199976, at *6 (W.D. Okla. Jan. 14, 2010) (excluding speculative expert testimony regarding defendant's knowledge and motivation); *United States* v. *Organon USA Inc.*, Civ. No. 07-12153-RWZ, 2015 WL 10002943, at *4 (D. Mass. Aug. 17, 2015) (excluding testimony about "what the 'regulators would have reasonably believed'").

Similarly in the *Rezulin* litigation, the court excluded expert testimony about "the motive, intent, and state of mind of" corporate defendants, because "the opinions of [expert] witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *In re Rezulin*, 309 F. Supp. 2d at 546. The court likewise excluded corporate intent opinions in the *Diet Drug* litigation, finding: "If the witnesses' bases for the opinions concerning improper intent comes from other evidence . . . ***that*** is what the jury should hear and the question of [defendant's] intent would flow from such evidence to be

[32] Perri Dep. at 187:13-188:24; *see also id.* at 189:21-191:20.

determined by the jury." *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) (emphasis in original). And in the *Fosamax* litigation, the court excluded expert opinions on corporate intent:

> To the extent Merck's motion seeks to preclude Dr. Parisian from testifying as to the knowledge, motivations, intent, state of mind, or purposes of Merck, its employees, the FDA, or FDA officials, it is GRANTED. Dr. Parisian conceded at the hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her report is replete with such conjecture. This is not a proper subject for expert or even lay testimony.

In re Fosamax, 645 F. Supp.2d 164, 192 (S.D.N.Y. 2009).

The Court should reach the same result here. Kessler and Perri have no expertise or knowledge that would permit them to read the minds of the Manufacturers or their employees based on the review of selected documents and deposition transcripts. Because a jury is perfectly capable of drawing its own inferences with regard to the motives, intent and thought processes of the Manufacturers without the benefit of specialized knowledge, the Court should bar Kessler and Perri from offering expert testimony on these issues. The Court should, at a minimum, hold Kessler to his word and, as the courts in *Wells* and *In re Prograf* did, preclude these experts from testifying as to corporate intent, motivation, and state of mind.

III. KESSLER MAY NOT OFFER LEGAL OPINIONS

Kessler may be able to provide general testimony about the FDA's regulatory framework. But the Court should not allow him to offer his legal opinion that the Manufacturers violated state or federal law. Kessler's testimony has been excluded on this basis by multiple courts. For example, one court concluded, "Kessler is not permitted to offer testimony about legal definitions and legal duties under state law." *Drake v. Allergan, Inc.*, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014). Other courts have reached the same conclusion. In the *C.R. Bard* litigation, the court excluded Kessler's testimony about "the interplay between FDA regulations and state tort liability"

and his opinion that "Bard violated FDA regulations," because "such testimony would be drawing legal conclusions." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628-29 (S.D. W. Va. 2013). And in the *Prograf* antitrust litigation, the court concluded, "Kessler appears to be an expert in how FDA normally functions, so he may testify on the factors FDA generally takes into account in evaluating citizen petitions. Beyond that, Dr. Kessler is not—and, indeed, cannot be—a legal expert." *In re Prograf Antitrust Litig.*, 2014 WL 7641156 at *2; *see also Wells*, 2013 WL 7208221, at *1. The Court should exclude Kessler's legal opinions here as well.

The overwhelming majority of Kessler's report is his one-sided recitation of the Manufacturers' marketing materials and practices. But Kessler also claims he will testify about the "responsibilities" of pharmaceutical companies under the FDCA,[33] which he then uses as nominal justification to support his legal conclusions that the Manufacturers violated federal and state law. *See, e.g.*, Kessler Rep. at ¶ 99 (Purdue "misbranded OxyContin as a drug that is safer and more effective than it actually is without substantial Evidence"), ¶ 221 ("Endo's sales force falsely marketed Opana ER as safer than other opioids"), ¶ 307 ("Janssen's marketing of Duragesic broadened its indications beyond the label").

Kessler's opinions about the duties of pharmaceutical companies are inadmissible legal conclusions. Kessler impermissibly "attempts to define the legal parameters within which the jury must exercise its fact-finding function." *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1246 (10th Cir. 2000). But "[t]he meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court." *Bammerlin v. Navistar Int'l Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994). Courts across the country consistently hold that legal conclusions and pronouncements of the law are not the proper subject

[33] *See* Kessler Rep. at 14.

of expert testimony. For example, courts bar legal opinions about a manufacturer's compliance with FDA regulations. *See Georges* v. *Novartis Pharm. Corp.*, No. CV 06-5207 SJO (VBKx), 2012 WL 9064768, at *9 (C.D. Cal. Nov. 2, 2012) ("[Plaintiffs' expert] is not permitted to offer legal conclusions on any topic, including whether Defendant was in regulatory compliance with the FDA."); *Lyman* v. *Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 2971550, at *6 (D. Vt. July 20, 2012) (excluding proffered regulatory expert's testimony that "expresses a legal conclusion or communicates a legal standard"); *Steele* v. *Depuy Orthopedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) ("[W]hether the FDA's approval of a PMA supplement imposes requirements on a particular device is a question of law to be determined by the Court, not a question of fact for the jury."). As the *Rezulin* court observed, "opinions concerning . . . the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert . . . expert testimony must be circumscribed carefully to ensure that the expert does not usurp either the role of the trial judge in instructing the jury as to the applicable law and the role of the jury in applying that law to the facts before it." *In re Rezulin*, 309 F. Supp. 2d at 557.

The relationship between FDA regulations and state tort laws are also legal questions for the Court. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). These purely legal topics are not proper subjects of Kessler's "expert" testimony, as the *Bard* court found when it excluded Kessler's opinion concerning the interplay between federal and state-law obligations. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 628-29.

At bottom, Kessler may be qualified to explain the basic structure of the FDA's regulatory regime or offer other testimony not at issue here. But the Court must police the line between proper areas for expert testimony and legal conclusions. Kessler should not be permitted to instruct

the jury about the requirements of state tort law, or opine on the interplay between federal food and drug regulations and state tort laws. This is precisely the balance other courts evaluating Kessler's testimony have struck. The *Bard* court excluded Kessler's legal opinions about the requirements of state and federal law but allowed him to testify about the general "FDA . . . framework and process" for approving medical devices. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 629. Courts have struck a similar balance when evaluating the testimony of other FDA experts. *See, e.g.*, *Georges v. Novartis Pharms. Corp.*, 2012 WL 9064768, at *9-10 (C.D. Cal. Nov. 2, 2012) (permitting FDA expert to "testify generally regarding pharmaceutical drugs within the context of the FDA" but prohibiting expert from "offer[ing] legal conclusions on any topic, including whether Defendant was in regulatory compliance with the FDA"). The Court should limit Kessler in the same way here.

IV. KESSLER'S OPINIONS ABOUT NORAMCO SHOULD BE EXCLUDED BECAUSE HE DID NOT DISCLOSE THEM IN HIS EXPERT REPORT

Kessler intends to offer the undisclosed opinion—which he revealed for the first time at his deposition—that Johnson & Johnson's former subsidiaries Noramco and Tasmanian Alkaloids drove the increase in oxycodone by selling active pharmaceutical ingredient (API) to Purdue.[34] Kessler is precluded from offering this testimony at trial because, under Rule 37(c), if a party fails to provide information required by Rule 26(a) or (e), "the party is not allowed to use that information" "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c). Under this standard, Kessler is precluded from offering testimony or opinions about Noramco and Tasmanian Alkaloids because he failed to disclose those opinions anywhere in his 320-page expert

[34] *See* Kessler Dep. at 100:22-101:4; 526:10-527:20; 528:1-23.

report. Indeed, Kessler's expert report fails to mention Noramco or Tasmanian Alkaloids even once.

CONCLUSION

For the foregoing reasons, the Manufacturers' request that the Court exclude the testimony of Perri and Kessler.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Lindsey B. Cohan, hereby certify that the foregoing document as served via the Court's ECF system to all counsel of record.

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